PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference ZAGURY8 PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2005/005890	International filing date *(day/month/year)* 25 February 2005 (25.02.2005)	Priority date *(day/month/year)* 27 February 2004 (27.02.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant VAXCONSULTING		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 30 August 2006 (30.08.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Athina Nickitas-Etienne
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Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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WASHINGTON, DC 20001-5303

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	24 JAN 2006
Applicant's or agent's file reference ZAGURY8 PCT	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US05/05890	25 February 2005 (25.02.2005)	27 February 2004 (27.02.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 38/04, 38/08, 38/10; C07K 14/00 and US Cl.: 530/300, 326, 327, 351

Applicant

VAXCONSULTING

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	22 November 2005 (22.11.2005)	Gregory S. Emch Telephone No. (571) 272-1600

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/05890

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☒ on paper

☒ in electronic form

c. time of filing/furnishing

☒ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☒ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/05890

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 4	YES
	Claims 1-3, 5-8, and 10-21	NO
Inventive step (IS)	Claims 4	YES
	Claims 1-3, 5-8, and 10-21	NO
Industrial applicability (IA)	Claims 1-8 and 10-21	YES
	Claims NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No
PCT/US05/05890

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

There is no claim number 9.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No
PCT/US05/0589(

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 10-21 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims indefinite for the following reason(s): There is no claim 9 and claims 10-21 depend from claim 9.

International application No
PCT/US05/[illegible]

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-3, 10-12, and 14-17 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 5,519,119 to Yamada et al.

The claims are drawn to a peptide originating from mammalian IL1-beta or TNF-alpha cytokines, homologous to one of the following peptides of human IL1-beta or TNF-alpha cytokines, wherein the human TNF-alpha cytokine peptide sequence is SEQ ID NOs: 2 or 5 and derivatives and pharmaceutical compositions thereof, wherein the peptides are less than 30 amino acids.

The claims lack novelty because Yamada et al. discloses TNF-alpha peptides (column 1) that are 100% identical to Applicant's SEQ ID NO: 2 (columns 49-52, SEQ ID NO: 10, residues 70-85) and Applicant's SEQ ID NO: 5 (columns 49-50, SEQ ID NO: 9, residues 128-139), thus anticipating claims 1, 2, and 11. Yamada et al. also discloses that the polypeptides may contain deletions, insertions, substitutions, or combinations thereof (column 5, lines 5-6), thus anticipating claims 10 and 12. Yamada et al. discloses anti-tumor pharmaceutical compositions comprising the TNF-alpha peptides as active ingredients (column 9, line 52 - column 10, line 26), thus anticipating claims 14-17.

Claims 1, 5-7, and 10-12 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 5,217,714 to Imura et al.

The claims are drawn to a peptide originating from mammalian IL1-beta or TNF-alpha cytokines, homologous to one of the following peptides of human IL1-beta or TNF-alpha cytokines, wherein the human IL1-beta cytokine peptide sequence is SEQ ID NOs: 4, 8, or 9 and derivatives and pharmaceutical compositions thereof, wherein the peptides are less than 30 amino acids.

The claims lack novelty because Imura et al. discloses human IL1-beta peptides (column 1) that are 100% identical to Applicant's SEQ ID NO: 4 (SEQ ID NO: 3, residues 121-135), Applicant's SEQ ID NO: 8 (SEQ ID NO: 3, residues 54-57), and Applicant's SEQ ID NO: 9 (SEQ ID NO: 3, residues 89-106), thus anticipating claims 1, 5-7, and 11. Imura et al. also discloses that the polypeptides may contain derivatives and deletions thereof (column 3, lines 22-46), thus anticipating claims 10 and 12.

Claims 1, 8, and 11 lack novelty under PCT Article 33(2) as being anticipated by Smith et al.

The claims are drawn to a peptide originating from mammalian IL1-beta or TNF-alpha cytokines, homologous to one of the following peptides of human IL1-beta or TNF-alpha cytokines, wherein the human IL1-beta cytokine peptide sequence is SEQ ID NO: 10, wherein the peptide is less than 30 amino acids.

The claims lack novelty because Smith et al. teaches human IL1-beta peptides that are 100% identical to Applicant's SEQ ID NO: 10, thus anticipating claims 1, 8, and 11 (entire document, especially p.47621).

Claims 1, 2, and 10-21 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 6, 207,642 to Wiley.

The claims are drawn to a peptide originating from mammalian IL1-beta or TNF-alpha cytokines, homologous to one of the following peptides of human IL1-beta or TNF-alpha cytokines, wherein the peptides are less than 30 amino acids, wherein the human TNF-alpha cytokine peptide sequence is SEQ ID NO: 2 and derivatives, pharmaceutical compositions, and antibodies and methods of treating or preventing diseases associated with the peptides.

The claims lack novelty because Wiley discloses TNF-alpha peptides (column 1) that are 100% identical to Applicant's SEQ ID NO: 2 (columns 81-82, SEQ ID NO: 9, residues 71-86), thus anticipating claims 1, 2, and 11. Wiley also discloses that the polypeptides

International application No.
PCT/US05/[illegible]

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

may exist as fragments and thus contain deletions (column 4, line 49), thus anticipating claims 10 and 12. Wiley discloses an immunogenic compound with a TNF-alpha peptide or fragment thereof (column 6, lines 19-33), thus anticipating claim 13. Wiley also discloses pharmaceutical compositions comprising the TNF-alpha peptides as active ingredients (column 25, lines 32-37), thus anticipating claims 14-17. Wiley discloses monoclonal and polyclonal antibodies to the TNF-alpha peptides (column 5, lines 16-18), and that these antibodies may be used in therapy to relieve diseases associated with TNF-alpha peptide production (column 36, lines 16-20) thus anticipating claims 18-21.